

**K152913 GORE TIPS Set, GORE TIPS Sheath, GORE TIPS Needle**Jul 21, 2016  
293 days to decisionK152913 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k152913/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Oct 2, 2015
Decision date	Jul 21, 2016
Days to decision	293 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Creganna Medical Aslo Business AS Creganna Tactx Medical</b>
Location	Galway, IE
Contact	ORLA HICKEY
510(k) history	2 submissions · 2 cleared · 2016-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152913/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026